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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 09/660,924 | 09/13/00 | DAHLBERG | FORS-04623 |

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| EXAMINER |
| SANDALC, W |

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| ART UNIT | PAPER NUMBER |
| 1636 | |

DATE MAILED: 11/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/660,924

Applicant(s)

Dahlberg et al.

Examiner

William Sandals

Art Unit

1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 17, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-107 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Interference

1. Claims 45-107 of this application have been copied by the applicant from U. S. Patent No. 6,110,677 and US Patent No. 6,121,001. These claims are not patentable to the applicant because the claims lack written description support in the instant specification.

An interference cannot be initiated since a prerequisite for interference under 37 CFR 1.606 is that the claim be patentable to the applicant subject to a judgement in the interference.

Specification

2. The use of the trademarks SEQUENASE, GENE READER, GEL DOCTOR, IMAGE MASTER, CFLP, QUIAAMP, CHELEX, TWEEN, NONIDET, DYNABEADS, LUMIPHOS, RIBOPROBE GEMINI SYSTEM, MARATHON MICRO A, and I-BLOCK have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 45-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 45-107 have been presented in a form of copied claims from issued patents (see above). Paper No. 7, filed August 17, 2001 has been submitted to provide information about the basis of support provided in the specification for the claimed subject matter. Paper No. 7 provides annotation within the body of the claims as to the location in the specification where support is derived for the claim language.

Claims 45, 49, 56, 65, 69, 76, 79, 84, 89, 95, 101, 105, 106 and 107 recite that the oligonucleotide has a 5' portion which does not hybridize to a polynucleotide. Alleged support for this claim limitation is cited at pages 110, and 111. No support is found at pages 110-111, however, page 110, lines 4-5 and page 109 lines 22-24 the specification teaches that each of the oligonucleotides (SEQ ID NO:'s 18-19) have a 3' portion which does not hybridize to the polynucleotide. This teaching is in contradiction to the claims. Therefore, no support is found for the claimed limitation.

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Claims 45, 49, 61, 69, 77 and 86 recite the limitation [the] "first fragment includes no more than 1 nucleotide from" [the second fragment]. No support for this limitation is found at page 111 or at figures 1A and 12B.

Claims 46, 50, 65, 80, 83, 89, 95, 101 and 107 recite the limitation "at least a 100 fold molar excess". No support for this limitation is found at the cited pages 42, 111 and 140.

Claims 55, 59, 67, 91, 98 and 103 recite a Markush Group. Regarding members of the Markush Group: "Specific binding pair", "chemiluminescers" and "coenzymes", no support is found at the cited pages 33, 42 and 52.

Claims 51, 64 and 65 recite a Markush Group. No support is found for the members of the Markush Group at the cited pages 33, 42 and 52.

Claims 52, 57 and 65 recite the limitation "at least 3° higher than the melting point". No support is found at the cited pages 42, 43 and 109-111.

Claims 53, 62, 65, 82, 88, 94 and 99 recite the limitation "hybridization sites are contiguous". No support for this limitation is found at the cited pages 42, 43 and figures 1A-1B.

Claims 76-78 are drawn to a kit. No support is found for this limitation at page 41.

Claims 79, 84, 93, 105 and 106 recite the limitation "the first fragment includes no more than 5 nucleotides of the non-hybridizing portion". No support for this limitation is found at page 111 or at figures 1A and 12B.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 46, 48-76, 79-83 and 89-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 46 recites the limitation "the amounts of fragments" in line 1. There is insufficient antecedent basis for this limitation in the claim.
8. Claim 46 recites the limitation "the amount of said polynucleotide" in line 2. There is insufficient antecedent basis for this limitation in the claim.
9. Claim 48 recites the limitation "the melting temperature" in lines 1-3. There is insufficient antecedent basis for this limitation in the claim.
10. Claim 49 recites the limitation "the melting temperature" in line 10. There is insufficient antecedent basis for this limitation in the claim.
11. Claim 50 recites the limitation "the molar amount of" in line 3. There is insufficient antecedent basis for this limitation in the claim.
12. Claim 52 recites the limitation "the melting temperature" in lines 4-6. There is insufficient antecedent basis for this limitation in the claim.
13. Claim 56 recites the limitation "the melting temperature" in line 12. There is insufficient antecedent basis for this limitation in the claim.

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14. Claim 57 recites the limitation "the melting temperature" in line 3. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 65 recites the limitation "the melting temperature" in lines 5, 8 and 10. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 73 recites the limitation "the melting temperature" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

17. Claim 79 recites the limitation "the melting temperature" in line 5. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 89 recites the limitation "the suspected concentration" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

19. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

October 29, 2001


TERRY MCKELVEY
PRIMARY EXAMINER